

Asset Usage Permission Form

Requestor Agreement

I agree to the following Asset Usage Requirements:

- Requestor must add next to each permitted Asset the copyright statement appearing in the "Copyright Notice" section provided by Ethicon where you requested the Asset
- Requestor must identify Asset with proper trademark as follows: LINX® Reflux Management System
- Usage and distribution of the Asset is limited to the Work identified above in the Country(s) of Distribution, and is non-exclusive, non-assignable, and non-transferrable. No other usage and distribution of the Asset is permitted without the express prior written permission of Ethicon, Inc. All copyrights and trademarks must be Ethicon, Inc. marks for Ethicon, Inc. to grant permission.
- Requestor must not alter or modify Asset in any way (other than resizing)
- Ethicon, Inc., reserves the right to revoke permission to use and distribute the Asset at any time and upon revocation of such permission, Requestor agrees to immediately stop all use, reproduction, distribution, public performance, and public display of the Asset.
- Requestor agrees that it will hold Ethicon, Inc. and its affiliates and their respective officers, directors, employees, and agents harmless from and indemnify them with respect to any losses, damages, claims, expenses, or costs (including reasonable attorney's fees) that may arise out of Requestor's use of the applicable Asset.
- Usage of Asset will be in favorable context and will be in a manner consistent with the good name, good will, reputation, and image of Ethicon, Inc.
- Asset will not be portrayed in a negative or disparaging manner to Ethicon, Inc., or any product of Ethicon, Inc., or its affiliates

Requestor Information (all fields below are required to grant request). Requestor agrees to comply with federal law regarding use of images of US currency.

Upon receipt and approval of this completed and signed request form, we will countersign, if accepted and provide the asset to you.

Entity Name/Individual Name	
Address	
Email	Phone
Digital Signature Field (required)	Date
Title (required)	

Send signed Asset Usage Permission Form:

1. Use the EMAIL REQUEST button to email your completed form
or
2. Save this completed PDF booklet and email to customersupport@eesus.inj.com

Digital Signature of Ethicon Representative	Ethicon Use Only
Date	

EMAIL REQUEST

LINX® Reflux Management System Important Safety Information

The LINX® Reflux Management System is a laparoscopic, fundic-sparing anti-reflux procedure indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who are seeking an alternative to continuous acid suppression therapy (i.e. proton pump inhibitors or equivalent) in the management of their GERD.

Rx Only

Contraindications: Do not implant the LINX Reflux Management System in patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials.

Warnings: The LINX device is considered MR Conditional in a magnetic resonance imaging (MRI) system up to either 0.7 Tesla (0.7T) or 1.5 Tesla (1.5T), depending on the LINX model implanted. Scanning under different conditions may result in serious injury to you and/or interfere with the magnetic strength and the function of the device. In the event alternative diagnostic procedures cannot be used and MRI is required, the LINX device can be safely removed utilizing a laparoscopic technique that does not compromise the option for traditional anti-reflux procedures. It is recommended that patients receiving the LINX device register their implant with the MedAlert Foundation (www.medalert.org) or equivalent organization.

Failure to secure the LINX device properly may result in its subsequent displacement and necessitate a second operation.

Laparoscopic placement of the LINX device is major surgery and death can occur.

General Precautions: The LINX device is a long-term implant. Explant (removal) and replacement surgery may be indicated at any time. Management of adverse reactions may include explantation and/or replacement.

The use of the LINX device in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm. The LINX device has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm.

The safety and effectiveness of the LINX device has not been evaluated in patients with Barrett's esophagus or Grade C or D (LA classification) esophagitis.

The safety and effectiveness of the LINX device has not been evaluated in patients with electrical implants such as pacemakers and defibrillators, or other metallic, abdominal implants.

The safety and effectiveness of the LINX Reflux Management System has not been established for the following conditions:

- Scleroderma
- Suspected or confirmed esophageal or gastric cancer

- Prior esophageal or gastric surgery or endoscopic intervention
- Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences or High Resolution Manometry equivalent, and/or a known motility disorder such as Achalasia, Nutcracker Esophagus, and Diffuse Esophageal Spasm or Hypertensive LES
- Symptoms of dysphagia more than once per week within the last 3 months
- Esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.)
- Esophageal or gastric varices
- Lactating, pregnant or plan to become pregnant
- Morbid obesity (BMI >35)
- Age < 21

Potential Side Effects: Potential adverse events associated with laparoscopic surgery and anesthesia include adverse reaction to anesthesia (headache, muscle pain, nausea), anaphylaxis (severe allergic reaction), cardiac arrest, death, diarrhea, fever, hypotension (low blood pressure), hypoxemia (low oxygen levels in the blood), infection, myocardial infarction, perforation, pneumonia, pulmonary embolism (blood clot in the lung), respiratory distress, and thrombophlebitis (blood clot). Other risks reported after anti-reflux surgery procedures include bloating, nausea, dysphagia (difficulty swallowing), odynophagia (painful swallowing), retching, and vomiting.

Potential risks associated specifically with the LINX Reflux Management System include achalasia (lower part of esophagus does not relax), bleeding, cough, death, decreased appetite, device erosion, device explant/re-operation, device failure, device migration (device does not appear to be at implant site), diarrhea, dyspepsia (indigestion), dysphagia (difficulty swallowing), early satiety (feeling full after eating a small amount of food), esophageal spasms, esophageal stricture, flatulence, food impaction, globus sensation (sensation of a lump in the throat), hiccups, inability to belch or vomit, increased belching, infection, impaired gastric motility, injury to the esophagus, spleen, or stomach, nausea, odynophagia (painful swallowing), organ damage caused by device migration, pain, peritonitis (inflammation of the peritoneum), pneumothorax (collapsed lung), regurgitation, saliva/mucus build-up, stomach bloating, ulcer, vomiting, weight loss, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).

References: 1. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol*. 2013;108(3):308-328, quiz 329. 2. Warren HF, Reynolds JL, Liphman JC, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. *Surg Endosc*. 2016;30(8):3289-3296. 3. Mody R, Eisenberg D, Hou L, Kamat S, Singer J, Gerson LB. Comparison of health care resource utilization and costs among patients with GERD on once-daily or twice-daily proton pump inhibitor therapy. *Clin Gastroenterol Hepatol*. 2013;11(6):1059-1069. 4. Badillo R, Francis D. Diagnosis and treatment of gastroesophageal reflux disease. *World J Gastrointest Pharmacol Ther*. 2014;5(3):105-112. 5. Ganz RA, Edmundowicz SA, Taiganides PA, et al. 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Laparoscopic magnetic sphincter augmentation versus double-dose proton pump inhibitors for management of moderate-to-severe regurgitation in GERD: a randomized controlled trial. *Gastrointestinal Endoscopy*. 2018. doi:10.1067/gie.2018.07.007. 25. Róna K, Reynolds J, Schwameis K, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. *Surgical Endoscopy*. 2017; 31(5):2096-2102.

Manufactured by:

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Asset Usage Request Form - LINX® Reflux Management System Images

Today's Date

This is a request to provide _____ permission to use the following asset(s).
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LINX® device
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Start Date for Asset Use:



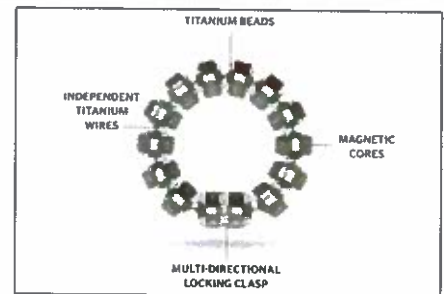
LINX® expanded
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Start Date for Asset Use:



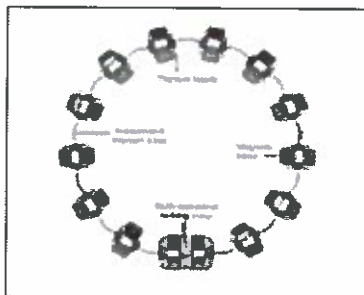
LINX® cutaway_closed
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LINX® + Quarter
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LINX® in hand_gray backgrd
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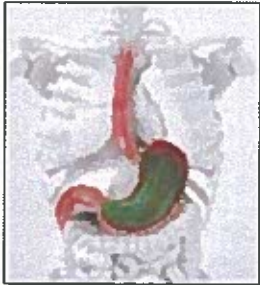
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Asset Usage Request Form - LINX® Images (continued)

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LINX® with Anatomy: Stomach and Full Esophagus
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LINX® with Anatomy: Stomach and Distal Esophagus
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LINX® + Bolus with Anatomy: Stomach and Distal Esophagus
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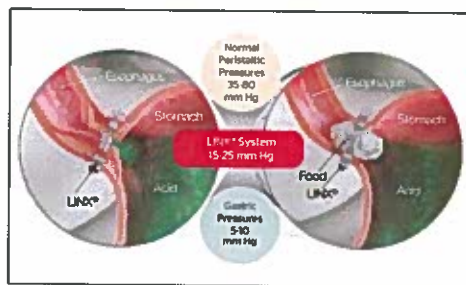


GERD_Anatomy_Stomach_Distal_Esophagus
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Asset Usage Request Form - LINX® Videos

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What is Reflux Patient Video
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How it works Patient Video
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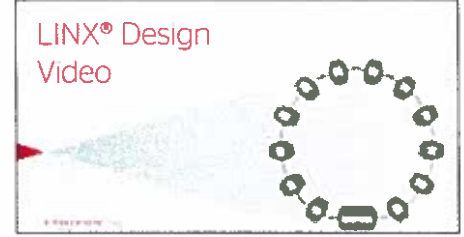
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